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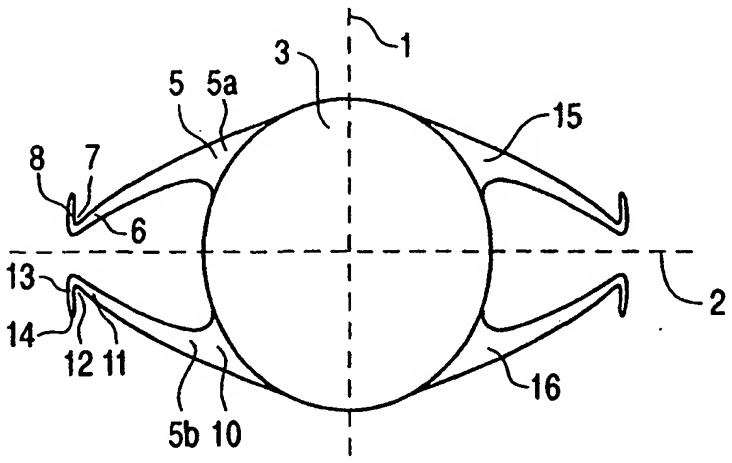
(57) Abstract

The invention relates to a method and apparatus for correcting the vision of an eye by implanting an artificial intraocular lens device in the anterior chamber of the eye. The intraocular lens device has a means for positioning the lens in the anterior chamber of the eye and a means for anchoring the lens in the anterior chamber of the eye.



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ANTERIOR CHAMBER INTRAOCULAR LENS APPARATUS AND METHOD

FIELD OF THE INVENTION

This invention relates to a method and apparatus for correcting ametropia using an anterior chamber intraocular lens and, more particularly, to an iris fixated anterior chamber lens. The haptic design of the lens device enables fixation onto the peripheral iris.

BACKGROUND OF THE INVENTION

Ametropia, an undesirable refractive condition of the eye, has three main subdivisions: myopia, hyperopia, and astigmatism. Ametropia is usually corrected by glasses or contact lenses. However, these refractive disorders may also be corrected by surgery. Refractive eye surgery is defined as that surgery on the eye which acts to change the light-bending qualities of the eye. Recently, many different surgical procedures have been attempted to eliminate the need for glasses or contact lenses in high myopia and hyperopia. The various surgical procedures include clear lens extraction, phakic intraocular lens implantation, and keratorefractive surgery including keratomileusis, epikeratoplasty, radial keratotomy, photorefractive keratoplasty, or intracorneal rings.

Keratorefractive procedures encompass any surgical procedure performed on the cornea which attempts to induce a refractive change. Many of the refractive surgical procedures share common optical problems: glare and haloes, over-correction, under-correction, loss of best corrected visual acuity, fluctuation in visual acuity, and regression of effect over time. Even for an experienced surgeon performing a high volume of such procedures, there are risks and associated problems with keratorefractive surgery.

Currently, reversible refractive procedures are looked upon more favorably by both refractive surgeons and the potential patient population. Any ideal refractive surgical procedure that attempts to correct myopia on an otherwise healthy eye should be reversible. Intracorneal rings have been shown to be reversible and return patients to their pre-surgical

refractive error without decreasing best corrected visual acuity. However, intracorneal rings have been shown to be effective mainly in the low to moderate myopic population. Phakic anterior chamber intraocular lenses have also been used for the correction of high myopia and have the desirable characteristic of reversibility.

It is well known to those skilled in the field of ophthalmology that there is a need for a successful anterior chamber ocular implant in the phakic eye to correct refractive errors such as high myopia. The process of implanting an intraocular lens in the anterior chamber of an eye without removing the natural-crystalline lens has been attempted on several occasions in the 1950's in Italy, Spain, and West Germany. These employed a semi-flexible style intraocular lens. Also, Dr. Peter Choyce reported six cases of phakic IOL implantation for myopia using the Choyce Mark VIII lens.

Several studies on different myopic implant models have been carried out since 1986, mainly in Europe. Fechner et al and Worst et al developed an iris claw anterior chamber lens which has been used since 1978. It is fixated to the iris by pincer/claws. Fyodorov designed an implant that is placed on the surface of the natural lens and held in place at the front by the iris. Various other projects for the phakic correction of ametropia using various intraocular lens designs are currently ongoing including a collamer implant (collagen polymer and hydrogel) which is undergoing development by STAAR. The Adatomed company is making a silicon implant in collaboration with Dr. Fechner.

In a landmark paper published nearly 40 years ago, Barraquer described the use of anterior chamber IOL's including the Strampelli one-piece lens, the Dannheim closed-loop lens, and the Barraquer open-loop lens, in aphakic and phakic myopic eyes (Ref: Barraquer J: Anterior chamber plastic lenses: Results of and conclusions from five years experience. Trans Ophthalmol Soc UK 1959;79:393-425). The concerns that he expressed in 1959 are still valid today. Barraquer was concerned first with the overall length of the lens and its relationship to anterior chamber diameter, because these lenses must remain in a stable position without disturbing the pupil. He concentrated his analysis on the ability of the lens to conform to the anterior chamber atraumatically, and finally, the need for a relatively simple

surgical implantation technique.

Phakic IOL's can generally be classified into three different types: 1) angle supported, 2) iris supported, and 3) phakic posterior chamber IOL's. Iris supported phakic IOL's have the advantages of minimum difficulty with sizing of the IOL (unlike angle supported IOL's) and less risk of inducing a cataract (unlike phakic posterior chamber IOL's).

Lens implantations are not only difficult and delicate operations, but the use of the currently available anterior chamber lenses includes several disadvantages. One of these is that due to the various eye size of different patients a large inventory of lenses is required by the surgeon to be immediately available in the operating room during the operation. Since the internal diameter of the anterior chamber angle (the diameter of the grove formed between the iris and the scleral spur) varies from patient to patient, anterior chamber lenses are manufactured in increments that span the normal size range for human eyes. Many of these lenses are furthermore available in powers varying from 14 thru 23 diopters in half diopter increments. It is difficult to precisely measure the diameter of the anterior chamber angle in which an angle supported anterior chamber lens will be placed prior to the time when the patient is actually in the operating room. It is only after the incision has been made that the anterior chamber angle can be measured. Anterior chamber IOL's have a flexible haptic design to compensate for error in measuring anterior chamber diameter and for permitting some flexure following normal deformation of the eye. Anterior chamber IOL's that are angle supported can also cause damage to a large area of the anterior chamber angle and an increased risk of developing glaucoma. Finally, angle supported anterior chamber IOL's can rotate within the eye, causing further trauma to the angle. Also, an inappropriately sized anterior chamber angle-supported IOL can cause too much pressure against the angle structure where the cornea and iris intersect inducing various elements of the uveitis-glaucoma-hyphema syndrome. An iris-fixated IOL that is easily implanted avoids both the disturbance of the angle structure and the sizing disadvantage of an iris that is angle-supported.

As mentioned, iris supported lenses avoid many of the problems associated with

angle-supported anterior chamber IOL's, including the problem of needing to precisely determine the anterior chamber angle and needing a suitably flexible haptic design. Iris-supported lenses have been in use since Epstein first conceived of the idea in 1953. Since that time, loops, clips, and sutures have been employed to maintain the position of the lens while the iris is used for support. Unfortunately, dilatation of the pupil produces the risk of dislocation with this type of lens. Another advantage of the iris-fixated lenses is a theoretical reduction in the risk of inducing glaucoma and anterior chamber angle damage caused by the haptics of angle-supported IOL's.

Worst introduced his iris-fixated lens in 1977. An important advantage of the iris fixated lens is derived from the surgeon's ability to properly and accurately center the lens over the pupil instead of having to rely upon an appropriately sized anterior chamber angle supported IOL. Because it is anchored to the iris and not in the angle of the anterior chamber, an iris fixated lens potentially provides the best centration of any current anterior chamber lens design. The greatest possible drawback to the claw lens is that the surgical procedure required for implantation is not easy. Thus, placement and attachment of the claw lens within the anterior chamber could be associated with complications in the hands of even experienced ophthalmologists and perfect centration over the visual axis is not ensured.

The advantages of a myopic implant for phakic eyes are several-fold. For younger patients, the technique respects the optical characteristics of the cornea and maintains accommodation. The placement of a phakic IOL does not damage the posterior segment and importantly is reversible. Should a complication occur, in most cases it is possible to return the eye to the original preoperative state by removing the implant. The reversibility of the procedure means that insertion of a myopic implant into the phakic eye can be considered an effective alternative in the treatment of ametropia, especially high myopia. If the implant is removed, it is always possible to remove the clear lens later on, or even perform refractive corneal surgery if it is found that these techniques give better results than myopic implants. Furthermore, as previously described, iris-fixated anterior chamber IOL's have the potential to have more advantages than angle supported anterior chamber IOL's. Iris-fixated IOL's

avoid the problems of needing accurate sizing and damage to the angle, both present in angle-supported IOL's. Iris-fixated IOL's also have the potential for better centration over the pupil since there is more direct surgeon control over the final placement of the lens.

Phakic IOL implantation for myopic correction is highly predictable and reversible, is a short operation with a brief healing time, and can be performed by most ophthalmologists. With phakic AC implants, refractive and visual acuity results are more stable with no fluctuations or delayed regression or progression of the refractive error. An iris-fixated phakic AC IOL for the correction of ametropia has the potential to avoid many of the problems of current refractive surgery. Since refractive surgery is performed on eyes without pathology, it is especially important that any potential surgical risk is minimized or eliminated. An iris-fixated AC IOL of the present invention may provide many of the benefits of an ideal refractive procedure while avoiding many of the common problems of anterior chamber IOL's.

The ideal keratorefractive procedure allows all the advantages of eyeglasses or contact lenses, namely, being able to correct a wide range of refractive errors, accuracy or predictability, allowing reversibility in the event that the refractive state of the eye changes and it becomes necessary to adjust the correction again, yielding minimal complications, and associated with technical simplicity, low cost, and being aesthetically acceptable to the patient. The goal of refractive surgeons should be to achieve 20/20 uncorrected visual acuity with long-term stability in greater than 95% of patients. None of the currently available refractive surgery procedures generate this degree of accuracy or stability.

The iris-fixated IOL of the present invention provides many of the benefits of the ideal refractive procedure. Because the procedure is carried out on eyes maintained in the phakic state, the method and apparatus of the current invention offers even more advantages, as also described. Because it is an iris-fixated IOL, it manages to avoid the problems of angle-supported IOLs as described above. Furthermore, while iris-fixated IOL's in the prior art do offer these significant advantages, there are still drawbacks to using them. The greatest drawback to the iris-fixated IOL is that the surgical procedure current iris-fixated lenses cause

complications, even with experienced ophthalmologists. The present invention manages to obviate many of these problems, as will be disclosed. In addition, perfect centration over the iris-fixated lenses, partly because of the level of surgical difficulty. This problem is also addressed by the disclosed invention.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved method of treating myopia.

Another object of the present invention is to provide a method of treating myopia which retains the eye's ability to accommodate and which minimally disturbs the corneal shape of the eye.

Yet another object of the invention is to provide an intraocular lens device for use in the phakic treatment of ametropia which avoids the failures and shortcomings of phakic intraocular lenses used for the surgical correction of myopia.

Another object of the invention is to provide an intraocular lens device for implantation in the eye which can be removed from the eye at some time after implantation if necessary.

Still a further object of the present invention is to provide an intraocular lens device for implantation into the eye which will correct myopia but will avoid common optical complications of refractive procedures including glare, haloes, irregular and regular astigmatism, and lack of refractive stability over time.

These and other objects of the present invention are achieved by an artificial, intraocular lens device for placement in the anterior chamber of an eye to treat myopia without removing the natural lens of the eye comprising a negative refracting lens, the lens having a relatively thick peripheral portion and a relatively thin central portion and the relatively thick peripheral portion having an outer rounded edge conforming to an internal curve of the cornea of the eye. The intraocular lens device also includes means connected to

the refracting lens for positioning the lens in the anterior chamber of the eye such that the negative refracting lens will not contact the natural crystalline lens of the eye and means connected to the suspending means for anchoring the device in the anterior chamber allowing later removal if necessary.

Preferably, the suspending or positioning means comprises four haptics secured to the negative refracting lens with two haptics relatively close to each other and the other two haptics located on the opposite edge of the optic. Each haptic has connected on its distal end an anchoring foot with each anchoring foot directed away from the anchoring foot on the closer haptic. After the IOL is surgically introduced into the anterior chamber, the haptics are fixed onto the iris by the following mechanism. Using a specially designed instrument, the distal end of one pair of haptics are grasped and compressed such that the haptics are brought closer together and then slowly released while gently pushing the pair of haptics posteriorly into the peripheral iris. As the pair of haptics are released and as the haptics re-approximate their original configuration, the anchoring feet imbed themselves in opposite directions into the iris tissue. The procedure is then repeated on the opposite pair of haptics while confirming that the optic is centered over the pupil.

In accordance with the present invention, there is provided a method for treating myopia comprising surgically implanting the novel artificial, intraocular lens device of the present invention into the anterior chamber of an eye and removably anchoring the lens device in the midperipheral iris of the eye.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1(a) is a top plan view of the lens device of the present invention.

FIG. 1(b) is a side elevational view of the lens of FIG. 1(a).

FIG. 1(c) is an end view of the lens of FIG. 1(a) and 1(b).

FIG. 2(a) is a front elevation view of the lens device of the present invention positioned within the eye anterior to the iris.

FIG. 2(b) is the view of FIG. 2(a) illustrating compression of the distal end of the haptics.

FIG. 2(c) is the view of FIG. 2(b) after releasing the compression of the haptics, illustrating haptic foot-like projection insertion into the peripheral iris tissue.

FIG. 3 is an enlarged view of FIG. 2(c) showing a magnified view of the haptic foot-like projection insertion into the peripheral iris tissue.

FIG. 4 is a cross-sectional view of the eye and shows an embodiment of a lens according to the present invention implanted in the anterior chamber of the eye.

FIG. 5(a) is a top plan view of the lens device of the present invention.

FIG. 5(b) is a top plan view of an alternative embodiment of the invention with more than one foot-like projection on each haptic.

FIG. 5(c) is a top plan view of an alternative embodiment of the invention showing haptics having differing longitudinal lengths.

FIG. 5(d) is a top plan view of an alternative embodiment of the invention illustrating haptics that are continuous along the longitudinal length of the lens device.

FIG. 6(a) is another top plan view of an alternative embodiment of the invention having haptics with a wider base at the haptic-optic junction.

FIG. 6(b) is a top plan view of an alternative embodiment of the lens device having a wider haptic body.

FIG. 6(c) is a top plan view of an alternative embodiment of the lens device with haptics having support protrusions for the compressing instrument.

FIG. 6(d) is a top plan view of an alternative embodiment of the lens device with haptics having indentations to aid in grasping of the haptics by the compressing instrument.

FIG. 7(a)-7(d) are top plan views of various alternative embodiments of the

invention illustrating various distal haptic designs.

FIG. 8(a) is a top plan view of an alternative embodiment of the invention with a haptic foot-like projection design that wraps around a small portion of peripheral iris tissue.

FIG. 8(b) is an end view of the view of FIG. 8(a).

FIG. 8(c) is a top plan view of the lens embodiment of FIG. 8(a) implanted within the anterior chamber of an eye illustrating the foot-like projection placement both beneath and above the iris tissue.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, the present invention is an artificial intraocular lens device (IOL) designed for placement in the anterior chamber of the eye. The lens has specially designed haptics that enable fixation of the lens onto the anterior surface of the iris. The lens is suspended in the anterior chamber by haptics having ends for anchoring the device in the midperipheral to peripheral iris anterior tissue. The iris-fixated lens is especially useful for the treatment of myopia. The lens is a minus refracting lens but may also be a plus refracting lens for the correction of hyperopia. The lens device is utilized in the phakic state (the state of the natural crystalline lens being retained). However, the lens device may also be used following cataract surgery or in the aphakic state. The patient's natural crystalline lens is located in the posterior chamber behind the iris and the artificial intraocular lens is located in the anterior chamber in front of the iris. The presence of the phakic state allows for accommodation to occur. Also, a phakic IOL for the correction of myopia is a much less invasive procedure than complete lens removal followed by IOL implantation.

The artificial, intraocular lens device includes a lens 3 which constitutes the main body and the optical portion of the lens device. The optical portion of the lens comprises a relatively thinner central portion and a relatively thicker peripheral portion to provide a minus power refracting lens. However, plus power refracting lenses may be provided for the correction of hyperopia.

Preferably, the lens measures substantially 5.0 to 7.0 mm in diameter and contains an ultraviolet filter, which reduces the passage of ultraviolet light, commonly known to be a desirable feature. The refracting properties of the lens is altered depending upon the natural refractive state of the pre-operative eye. Ideally, a patient's refraction would be adjusted to an emmetropic state. Using a nomogram, it is possible to predict the power of the lens device required using several common parameters including keratometric readings, pre-operative refraction, and measurement of both the axial length of the eye and the anterior chamber depth.

The optic of the lens device is preferably made of a solid, optical, non-biodegradable material such as polymethylmethacrylate (PMMA) and may be either lathe-cut or injection molded. Other materials, such as polysulfone may be used. Foldable or flexible lenses may also be used for the optic of the lens device, permitting a smaller entry incision into the eye for the lens. The optic and the haptics may be comprised of one-piece or the optic may be fabricated and the haptics attached at a later point.

Intraocular lenses have been extensively used following cataract surgery in the anterior chamber of the eye. Anterior chamber IOL's have also been used in the phakic eye for the treatment of ametropia. In general, an intraocular lens consists of a lens body and a plurality of support members usually projecting from different sides of the lens body for use in supporting the lens in position in the eye. Within the basic format, several different designs of lenses are available. In most of these, the position fixation elements or support means are in the form of rigid loops, arms, plates, and legs such as exemplified by the rigid loops in Jensen, US. Pat. No. 4,110,848, and by rigid plates of Kelman, U.S. pat. No 4,092,743. Prongs extending through the iris are disclosed as a fixation means in the Flom, U.S. Pat. No. 3,866,249.

The following U.S. Patents disclose intraocular lens which employ different types of haptics or position fixation members: U.S. pat. Nos. 4,010,496, 4,085,467, 4,159,546, 4,174,543, 4,242,760, 4,244,060, 4,251,887, 4,253,200, 4,280,232, 4,285,072, 4,298,994, 4,298,995, 4,304,012, 4,316,292, 4,328,595, 4,338,687, 4,340,979, 4,361,913,

4,370,760, 4,377,873, 4,418,431. The purpose of the haptics or position fixation members is to hold or support the optic or lens body in the eye in a stable position with respect to the pupil and visual axis.

A flexible posterior chamber lens is disclosed by Shearing, U.S. pat. No. 4,159,546 in which J-shaped elastic support members extend outwardly from opposite peripheral edges of the lens to engage the ciliary body or the lens capsule to support the lens in position. Furthermore, it is known to fashion the support members of the lens so that they have sloped or inclined portions which result in the portions of the support members which are to contact the eye being no-planar with the lens body. Such lenses are said to be "vaulted" and are disclosed in U.S. pat. Nos. 2,834,023; 4,092,743; 4,110,848; and 4,134,161.

Referring to FIG. 1(a), the present invention is generally characterized by an intraocular lens for implant in the anterior chamber of an eye including a lens body 3 connected to a first 5 and second 10 fixation member on each half of the lens body; a first fixation member 5 connected to a first side peripheral edge of the optic 3 and the fixation member 5 extending substantially along the longitudinal axis 2; and a second fixation member 10 connected to a second side peripheral edge of the optic 3 extending substantially along the longitudinal axis 2. The first and second fixation members are oriented so that the distance between the points where the fixation members are connected (proximal end 5, 10) to the peripheral edge of the optic is greater than the distance at the distal end 6, 11 of the fixation members. The proximal portion of each fixation member extends tangentially from the point of its respective attachment to the peripheral edge of the optic and toward the longitudinal axis 2. Each fixation member has connected at its distal end 6, 11 a foot or foot-like projection 8, 13 which extends in a direction substantially transverse to and away from the longitudinal axis 2. As the foot-like projections 8, 13 extend substantially transverse to and away from the longitudinal axis, the projections may angle slightly above a plane perpendicular to the optical axis 17 or angle slightly below a plane perpendicular to the optical axis 17. As an example, in FIG. 1(c), the foot-like projection 8 extends substantially transverse to and away from the longitudinal axis and angles slightly below a plane

perpendicular to the optical axis. This angle 19 may vary from a few degrees up to 45 degrees. Referring to FIG. 1(a), as the projections extend substantially away from the longitudinal axis, the projections may angle slightly towards the optic or slightly away from the optic. As an example, the foot-like projection 8 in FIG. 1(a) is angled slightly towards the optic. The foot-like projections are adapted to be attached to the peripheral iris in the anterior chamber of an eye. As illustrated in Fig.1(b), the haptics 5 form a vault angle 18 with respect to the optic 3 of the lens device to prevent contact of the natural-crystalline lens with the intraocular lens device of the present invention, following implantation. Preferably, the vault angle ranges from about 2 to 4 degrees of 180 degrees. The vaulting or angulation of the fixation members also spaces the posterior surface of the lens body from the iris.

The lens body is held in place in the eye by means of two support legs or fixation members on each half of the lens body. These support legs are made of a firm spring-like material such as PMMA. Other materials having similar characteristics can be used if they are inert and substantially nonreactive in the eye. As seen in FIG. 1(a) the support legs 5, 10 each have foot-like projections 8, 13 located towards the distal end 6, 11 of each support leg, with the foot-like projection 8 of support leg 5 facing away from the foot-like projection 13 of support leg 10. The foot-like projections are integrally formed on the end of each support leg and serve to removably anchor the lens device onto the iris in the anterior chamber as will be described more fully hereinafter.

The implantation procedure is illustrated in FIG. 2(a)—2(c). Surgical implantation of an artificial intraocular anterior chamber lens (IOL) in the anterior chamber of an eye is a generally known technique to those skilled in the art. An operating microscope is used throughout the procedure. A scleral incision is made into the anterior chamber sufficient in size to allow entry of the IOL device of the invention. A visco elastic material such as Viscoat or Healon is injected into the anterior chamber, deepening the chamber and protecting the corneal endothelium. A lens glide, basically a sliding board on which the lens will pass into the eye, is then placed into the anterior chamber. Preferably, the suspending means of the present invention comprises four haptics 5 secured to the refracting lens with

two haptics relatively close to each other and the other two haptics located on the opposite edge of the optic. Each haptic has connected on its distal end an anchoring foot 8 with each anchoring foot directed away from the anchoring foot on the closer haptic. The anchoring feet between the two relatively closer haptics are separated by a distance 22 to allow the anchoring feet to be compressed together thereby storing the potential energy in the form of plastic memory such that when the anchoring feet are released, the distance between the anchoring feet prior to compression is reapproximated. The intraocular lens device is then grasped with a forceps and placed under the visco elastic material onto the lens glide. The leading haptics are delivered down to the distal end of the lens glide. The lens glide is removed.

As seen in FIG. 2(b), after the IOL has been surgically introduced into the anterior chamber, the haptics are fixed onto the peripheral iris in the following manner. Using a specially designed compressing instrument, the distal end 7, 12 of one pair of haptics are grasped and compressed thus bringing the distal ends closer together 23. The distal haptics are grasped at their ankles 7,12 using the specially designed haptic-compression instrument. The foot-like projections prevent the compressing instrument from slipping off the haptics during the flexure of the haptics by the instrument. The instrument is used to push the ankles of the distal haptics towards each other. The haptic-compression instrument then slowly releases the grasped distal haptics. Referring to FIG. 2(c), as the haptics are released, the foot-projections 8,13 embed themselves into the peripheral iris tissue 24, 25, thereby fixing the haptics in position. The haptics are slowly released while gently pushing the pair of haptics posteriorly into the peripheral iris. Pushing the foot-like projections posteriorly into the iris as the haptics are released facilitates the foot-like projections imbedding themselves into the iris tissue. As the pair of haptics are released and as the haptics reapproximate their original configuration, the anchoring feet imbed themselves in opposite directions into the iris tissue 24, 25. The process is repeated for the proximal haptics, all the while, determining that the optic is centered over the pupil. Unlike fixation of the Worst claw lens which requires one hand to use an instrument to hold the lens and an iris hook in the second hand to lift the

iris into the claws, the device of the current invention requires a compressing instrument in only one hand. Once the haptics are grasped with this instrument, the haptics are not only ready to be fixated onto the iris, the whole lens device is under the control of the surgeon. This allows improved centration over the pupil. Much like phacoemulsification, the second hand can be used to stabilize the operating hand, improving centration and appropriate fixation of the lens device onto the iris. At the completion of the procedure, a small peripheral iridectomy is placed near the incision. A laser peripheral iridotomy may be performed prior to the lens implantation procedure.

The surgical instrument for compressing the haptics and suspending the lens device upon the iris of the eye can have a variety of designs. Many instrument designs have been commercialized or proposed for instruments incorporating a pair of cooperating jaws (i.e., a jaw assembly) in which one jaw pivots or otherwise moves relative to the other jaw between open and closed positions. Examples of such instruments include tissue graspers, tissue clamps, needle holders, forceps, tissue cutters, and all these instruments in the form of an "endoscopic" design, such as retinal endoscopic forceps and retinal endoscopic scissors. "Endoscopic" instruments generally include a pair of coaxially arranged shafts, an end-effector at the distal ends of the shafts, and an actuator at the proximal ends of the shafts. The end-effectors may have a variety of configurations including needle drivers, forceps, scissors, and clip appliers.

A surgical instrument such as a forceps having a handle at its proximal end, a pair of jaws at its distal end for gripping the haptics, and a connecting member for transmitting user-applied force from the handle to the pair of jaws is required for the process of compressing the haptics and fixing the lens of the present invention upon the iris.

In a sub-embodiment of the lens device of the present invention, the distal end of the haptics may have attached foot-like projections which extend in a direction substantially transverse to and towards the longitudinal axis. In this particular sub-embodiment it is obvious that the distal haptics must be spread (as contrasted to compressed) prior to fixation onto the iris and slowly released. As the haptic pair is slowly released, the

distal ends will reapproximate their original position and the foot-like projections will embed themselves into the iris stroma.

FIG. 3 is an enlarged view of FIG. 2(c), showing the imbedded portion 14 of the foot-like projections 13 within the iris 20. FIG. 4 demonstrates the position of the iris-fixated lens 13 device of the present invention within the anterior chamber 31 of the eye. It can be seen that the lens device is sufficiently vaulted to provide an adequate distance between the lens device 13 and the natural crystalline lens 33 of the eye. The location of the fixation of the haptics of the lens 13 upon the iris 20 is also illustrated.

There are various possible subembodiments of the present invention, illustrated in FIG. 5—FIG 7. FIG. 5(a) demonstrates the typical shape of the iris-fixated anterior chamber IOL of the present invention. FIG. 5(b) illustrates a sub-embodiment that has two foot-like projections 8, 34 on each haptic leg 5. This further minimizes any chance of spontaneous dislocation of the iris-fixated lens. FIG. 5(c) illustrates haptic legs that are of different length. One haptic leg 35 is shorter than its paired haptic leg 36.

FIG. 5(d) shows an iris-fixated lens design that is especially useful in a foldable lens design. Although any of the sub-embodiments of the present invention may incorporate a foldable optic, the presence of a flexible optic design will decrease the amount of potential energy and recoil that can be stored in the haptic pair during the compression of the haptics. The haptics are not likely to re-approximate their pre-compression position as quickly when the haptics are attached to a flexible optic. The design of FIG. 5(d) illustrates a haptic that is continuous along the longitudinal axis which increases the amount of fixation area between the haptic and the optic. This provides greater stability of the haptic with respect to the optic during compression of a haptic pair prior to iris fixation. Although the purpose can also be achieved by adding reinforcing material between the haptics of a single pair near their attachment to the optic, presence of reinforcing material at that location will prevent folding of the lens along the longitudinal axis.

Again, referring to FIG. 5(d), the intraocular lens of this design can then be

folded along the longitudinal axis and inserted into the anterior chamber through a small incision into the eye. Creating a smaller insertion incision lessens the possibility of any potential refractive effect, such as induction of astigmatism, by the insertion incision. Deformable or foldable IOLs have gained widespread acceptance and use since it has been recognized that foldable IOL's have the potential of providing many benefits. An IOL including a deformable transparent lens body which may be folded or rolled into a reduced profile size may fit through a relatively smaller incision in ocular tissue and after insertion and release within the anterior chamber of the eye return to its original size and shape by virtue of its natural resilience. In addition, the use of a material that allows a more gradual return to its original shape and size after insertion into the eye provides an even safer surgical procedure. The use of a smaller incision would beneficially result in a safer overall surgical procedure requiring less suturing and reducing the likelihood of postoperative infections. Also, a smaller incision would reduce the incidence of postoperative astigmatism and substantially reduce the rehabilitation time. Furthermore, a small incision allows easier maintenance of a deep anterior chamber with a viscoelastic during surgery so that there is even less risk of trauma to the corneal endothelium during the surgical implantation procedure. Methods of folding deformable IOLs and inserting into the eye are well established.

The particular subembodiment of FIG. 5(d) is especially well-suited for the correction of myopia since it can potentially have many desirable characteristics of an ideal refractive procedure including minimizing complications such as glare and halo (more common with corneal procedures), requiring a smaller insertion incision, eliminating trauma to the trabecular meshwork (associated with glaucoma and hyphema), a simpler surgical procedure (many ophthalmologists are familiar with insertion incision formation and lens insertion), allowing reversibility in the event of an undesirable refractive outcome, and maintenance of accommodation (lens extraction for high myopia removes accommodation).

FIG. 6(a) illustrates a sub-embodiment of the invention similar to FIG. 5(a). The haptic in FIG. 6(a) has a larger area of fixation 39 to the optic 3. If the haptics and optic

are made of one piece, there is less concern of strength at the haptic-optic junction. However, if the haptics and optic are initially formed separately and then attached, the haptic-optic junction is relatively weaker. In either case, it is important that this junction is sufficiently strong to prevent separation or cracking while the distal haptic ends are compressed during the process of iris fixation. A larger area of contact 39 between the haptic and optic increases the strength of this important junction. FIG. 6(b) illustrates a haptic that has a wide haptic-optic junction and a haptic body of greater width than that illustrated in FIG. 5(a).

FIG. 6(c) illustrates a haptic design that aids in the process of compressing the haptics with the compressing instrument and fixating the haptics onto the iris. The protrusions 41, 42 along the outer edges of the haptics prevent the compressing instrument from slipping along the haptic while the instrument compresses the haptic pair. Grasping and compressing the haptic pair at a point more proximal to the optic is advantageous during haptic fixation onto the iris because it improves surgeon visibility of the foot-like projections. In the previous discussion of haptic fixation onto the iris, the compression instrument was used to grasp the distal haptics at the junction of the haptic leg and foot-like projection (refer to FIG. 1(a), 7 and 12). The instrument may obscure the surgeon's view of the foot-like projections when the haptics are grasped to close to their distal end. FIG. 6(d) also illustrates a haptic design that aids in the process of compressing the haptics during fixation of the haptics onto the iris. The indentations 43, 44 are present along the outer edges of the haptics at a point more proximal to the optic than the grasping point at the ankles (FIG. 1(a), 7 and 12). This particular haptic design is useful when using a compressing instrument having forceps jaws which are thinner and can fit into the indentations. This design may permit even greater control of the lens device during fixation onto the iris.

FIG. 7(a)—7(d) illustrate various sub-embodiments of the haptic design that ensure fixation of the haptics on the iris and minimize spontaneous disengagement of the haptic from the iris. FIG. 7(a) shows a haptic 5 that has a foot-like projection which ends in a relatively sharp point 45. Eyes with a dark iris color typically have a very smooth anterior iris surface. This is in contrast to eyes with a light iris color which have many crypts and

undulations on the anterior iris surface. When fixating the haptics upon the iris, a smooth anterior iris is less easily engaged during haptic compression and release. Methods to ensure engagement of the iris during release of the haptic compression include:

1) slight posterior force of the haptics into the iris tissue

2) engaging one haptic foot-like projection onto the iris by tilting the lens device along the longitudinal axis followed by engaging the other foot-like projection onto the iris by rotating the lens device along the longitudinal axis in the other direction then releasing haptic compression

3) increasing the angle at which the foot-like projections emerge from the haptic leg (illustrated in FIG. 1(c), 19) and lastly

4) increasing the sharpness of the tip of the foot-like projection.

Another method to prevent spontaneous disengagement of the haptic from the iris is shown in FIG. 7(b). The haptic foot-like projections are comprised of a bulb-like design 45, 48. This design is more useful in patients with a loose anterior iris stroma and many crypts in the anterior iris surface. Once the haptic feet embed themselves into the iris, the bulb-like projections aid in preventing easy dislocation of the haptic from the iris. FIG.7(c) illustrates a barb 49, 50 design on the tip of the foot-like projections which allow ease of insertion into the iris tissue but prevent easy dislocation once implanted. Shown in FIG. 7(d) is a haptic with foot-like projections 51, 52 that are slightly longer in length than in FIG. 1(a).

The last sub-embodiment shows a haptic design that acts as a "clip" onto the iris. In the previous sub-embodiments discussed, the foot-like projection is positioned for the most part, within the iris tissue itself—although a small part of the tip of the foot-like projection may emerge from the posterior surface of the iris tissue. In the sub-embodiment seen in FIG. 8, the foot-like projection wraps itself around the iris as will be further explained. Referring to FIG. 8(a), it can be seen that the foot-like projection 5 distally has

two angled portions. The first angled portion 53 and a second angled portion 56. Following fixation of this particular sub-embodiment onto the iris, one portion 55 of the foot-like projection is in contact with the anterior iris tissue while the 180 degree bend portion 56 is in contact with the iris stroma, and the portion 54 of the haptic distal to the 180 degree bend portion 56 is in contact with the posterior iris surface. This is also illustrated in FIG. 8(b). FIG. 8(c) shows the position of the haptic after fixation onto the iris. Again, it can be seen that one portion 55 contacts the anterior iris surface while the 180 degree bend portion 56 is buried within the iris tissue and the last section 54 of the foot-like projection contacts the posterior iris surface. The last section 54 is illustrated as a dotted line. In this particular design, the foot-like projection wraps itself around a small portion of peripheral iris tissue thus providing greater stability and less likelihood of spontaneous dislocation of the haptic from the iris. The method of compressing the distal haptic ends and fixation onto the iris is similar to the previous sub-embodiments.

The iris-fixated ACIOL of the present invention has multiple advantages including:

1. Reversibility—should a complication occur, in most cases it is possible to return the eye to the original preoperative state by removing the implant.
2. Minimum difficulty with sizing of the IOL (unlike angle supported IOL's).
3. Less risk of inducing a cataract (unlike phakic posterior chamber IOL's).
4. Avoidance of disturbance or trauma to the angle structures including the trabecular meshwork and less risk of glaucoma (unlike angle supported IOL's).
5. Potential for improved centration since there is more direct surgeon control over the final placement of the lens (unlike angle supported IOL's which rely upon perfect sizing).
6. The technique maintains accommodation.

7. An iris-fixated ACIOL respects the optical characteristics of the cornea and does not induce glare or haloe (unlike other corneal refractive procedures such as LASIK, PRK, and RK).

8. Potential for highly predictable refractive outcome (based on previous lens implant studies).

9. Short operation with a brief healing time which can be performed by most ophthalmologists with minimal training (many ophthalmologists are familiar with making an insertion incision into the eye and with the techniques of lens insertion).

10. A simpler surgical procedure since lens fixation onto the iris is a one-handed technique with the second hand used to stabilize the operating hand (unlike the Worst claw lens which has the primary disadvantage of requiring a more delicate iris fixation technique).

11. Visual acuity results are more stable with no fluctuations or delayed regression or progression of the refractive error.

12. Can correct a wide range of refractive errors including hyperopia, high myopia, and aphakia unlike many other refractive procedures.

13. Low cost for both the patient and the operating surgeon (since an expensive laser and concomitant maintenance is not required).

14. Potential for introducing the lens device through a small incision into the eye, further decreasing any potential complications of intraocular surgery, such as post-operative astigmatism.

A distinct advantage of the intraocular device of the present invention is that, since the lens device is implanted without removing the natural-crystalline lens from the eye, the ability of the eye to accommodate is retained. During the process of accommodation, the

natural-crystalline lens increases in anterior/posterior diameter. A vaulted position of the lens device prevents contact between the natural lens and the artificial lens device from touching during the process of accommodation.

Notwithstanding the great strides made in lens implantation, as evidenced by the thousands of successful lens implantations, complications in individual cases continue to arise in a small percentage of the cases. Improper sizing can cause subsequent mispositioning of the lens in some instances. This invention provides an improved anterior chamber IOL for positioning in the anterior chamber of the eye. The lens of this invention is especially easy to implant and has stability without requiring suturing.

It will thus be appreciated that there is provided an artificial IOL device and method of treating myopia which does not require removal of the natural-crystalline lens of the eye. No sizing is necessary, since the lens is iris-supported. The lens is non-biodegradable and biologically inert.

Numerous modifications of the preferred embodiments of the lens of the invention will undoubtedly occur to those skilled in the art. It should be understood that the scope of the invention is not limited to the preferred embodiments but is limited solely by the appended claims.

CLAIMS

What is claimed is:

1. An intraocular lens device for placement in an anterior chamber of an eye having an iris, comprising, a refracting lens, a plurality of haptics secured to the refracting lens wherein the plurality of haptics can be fixed to the iris.

2. The intraocular lens device of claim 1, wherein the lens has a peripheral portion and a central portion, and wherein the peripheral portion has an outer rounded edge that conforms to the internal curve of the eye.

3. The intraocular lens device of claim 2, further comprising a plurality of anchoring feet wherein the anchoring feet are connected to the distal end of the haptics.

4. The intraocular lens device of claim 2, wherein the device has four haptics secured to the lens, and wherein two of the haptics are relatively close to each other and the other two haptics are located on an opposite side of the lens.

5. The intraocular device of claim 1, wherein the lens is made from a solid, optical, nonbiodegradable material.

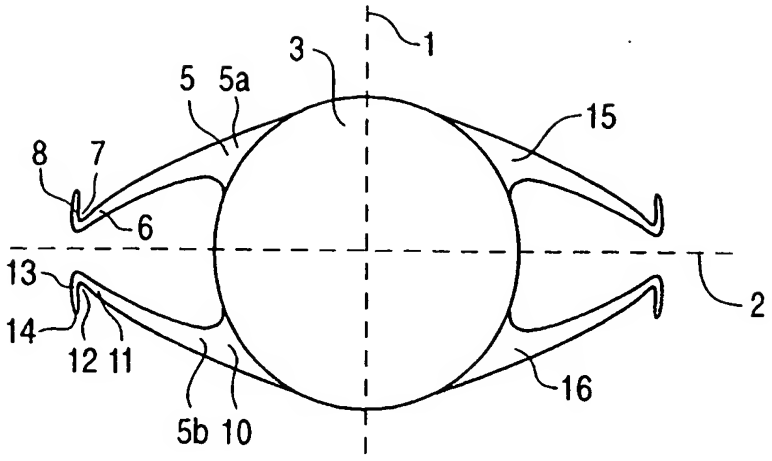

FIG. 1(a)

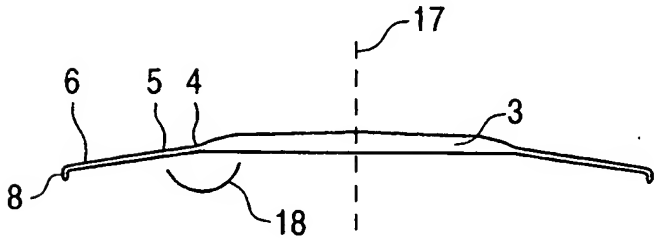

FIG. 1(b)

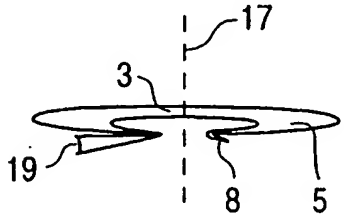

FIG. 1(c)

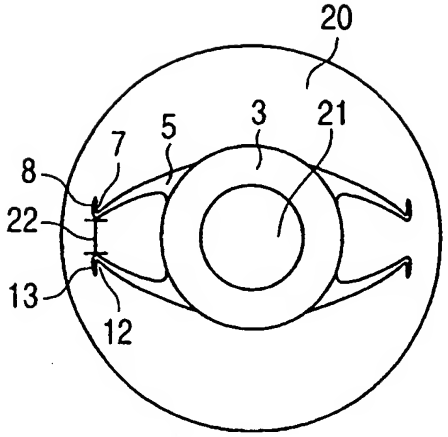

FIG. 2(a)

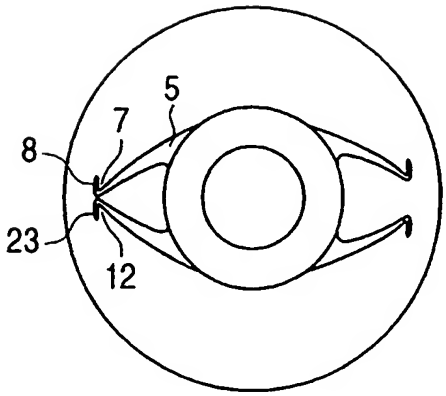

FIG. 2(b)

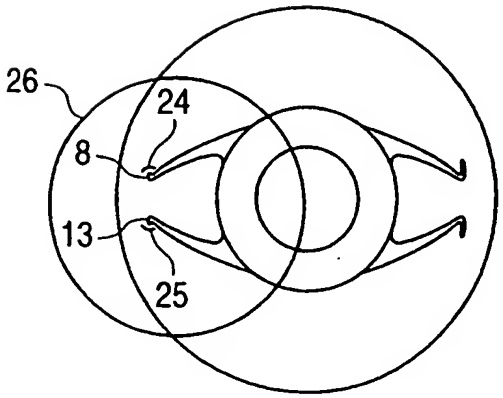

FIG. 2(c)

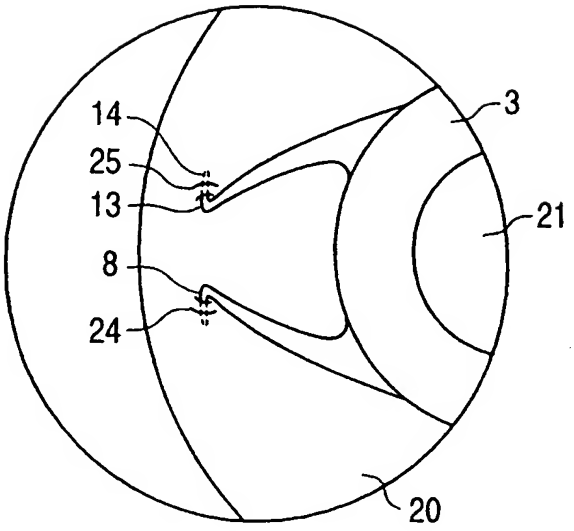

FIG. 3

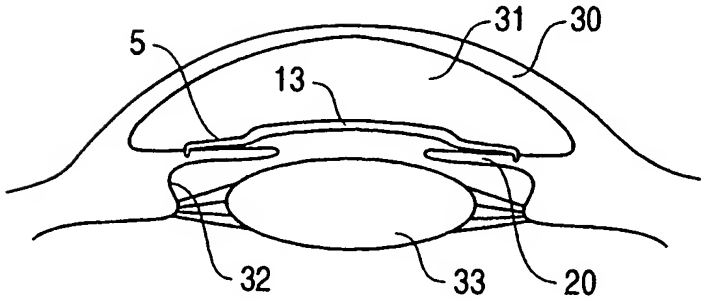

FIG. 4

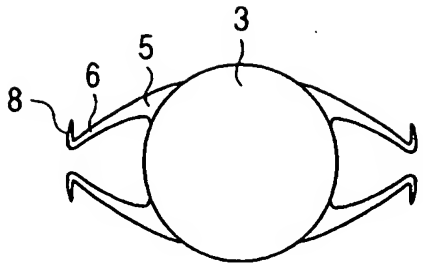

FIG. 5(a)

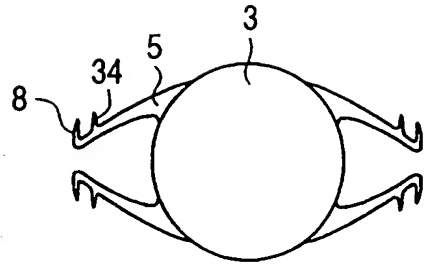

FIG. 5(b)

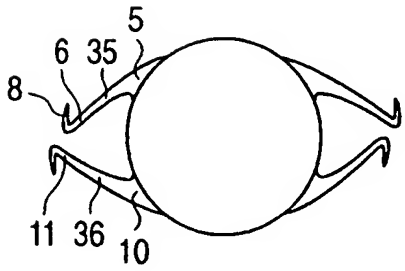

FIG. 5(c)

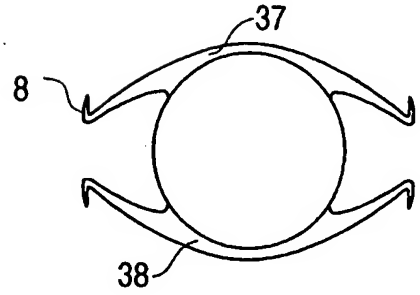

FIG. 5(d)

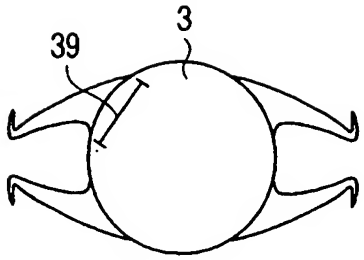

FIG. 6(a)

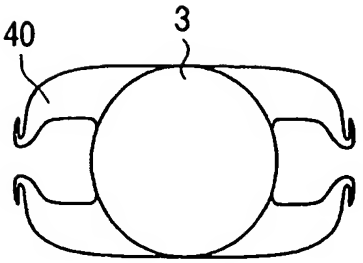

FIG. 6(b)

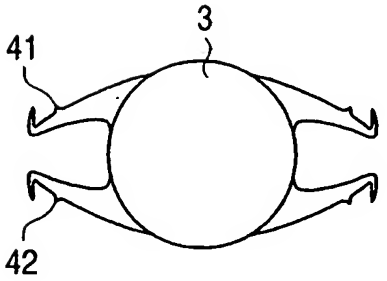

FIG. 6(c)

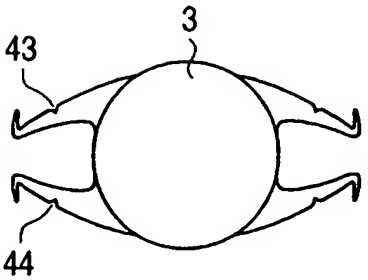

FIG. 6(d)

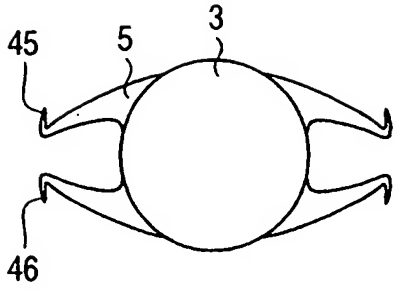

FIG. 7(a)

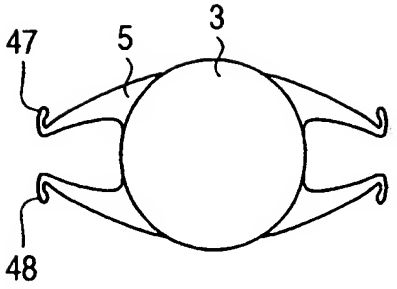

FIG. 7(b)

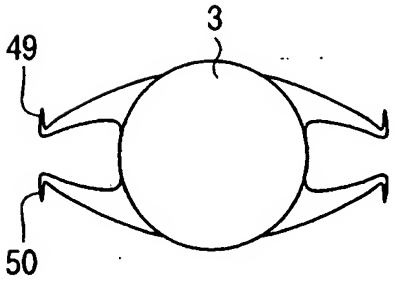

FIG. 7(c)

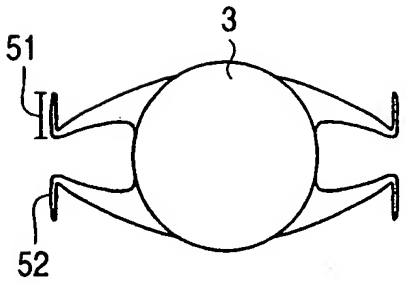

FIG. 7(d)

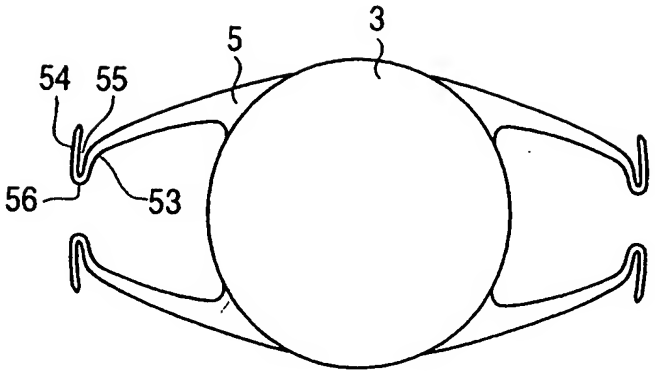

FIG. 8(a)

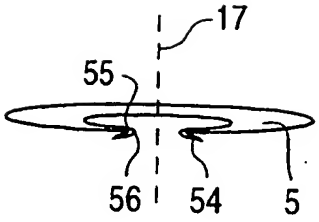

FIG. 8(b)

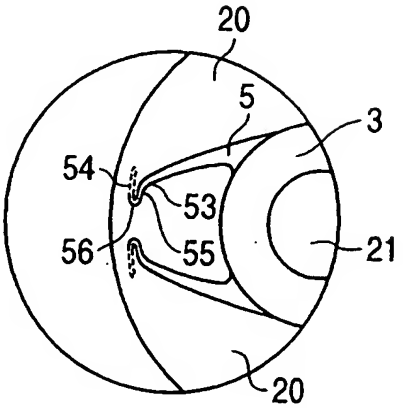

FIG. 8(c)

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/12046

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 20302 A (WORST JAN GERBEN FRANS) 26 November 1992 (1992-11-26)	1
A	claims 1,2,7; figures 1,2,2A	2-5
X	NL 8 602 113 A (JAN HENK LINDENHOVIUS) 16 March 1988 (1988-03-16)	1
A	page 10, line 16 - line 26; figure 10	2-5
X	US 3 922 728 A (KRASNOV MIKHAIL MIKHAILOVICH) 2 December 1975 (1975-12-02) the whole document	1
A	US 4 215 440 A (WORST JAN G F) 5 August 1980 (1980-08-05) abstract; figures	1-5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 September 1999	04/10/1999

Name and mailing address of the ISA	Authorized officer
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